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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,197	03/17/2004	Claus D. Buergelt	5853-371	3776

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	

ART UNIT	PAPER NUMBER
1645	

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03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,197	BUERGELT ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

Claims 1-5 are pending and under examination. Claims 6-20 have been cancelled

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

1. The rejection of claims 1 and 3 under 35 U.S.C. 103(a) as being unpatentable over Englund et al. Diagn. Microbiol Infect Dis vol. 33 p. 163-171, 1999 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937, Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31 is maintained for the reasons set forth in the previous office action mailed 10/31/07.

2. The rejection of claims 1 and 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Erume et al. African Health Science vol.1 pg. 83-89, 2001 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937, Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31 is maintained for the reasons set forth in the previous office action mailed 10/31/07.

3. The rejection of claims 1,3, 4 and 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Herrewegh et al. EP 1223225A1 published July 17, 2002 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937, Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31 is maintained for the reasons set forth in the previous office action mailed 10/31/07.

4. The rejection of claims 1,2,3 and 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Corti et al. BMC Microbiology 2002, 2:15 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937,Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31 is maintained for the reasons set forth in the previous office action mailed 10/31/07.

5. The rejection of claims 1 and 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937 in view of Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31 is maintained for the reasons set forth in the previous office action mailed 10/31/07.

Applicants traverse all the above rejections and submit that none of the five combination of references render the invention obvious because the references as combined fail to teach or suggest all the claim limitations that would have led one of ordinary skill to modify the prior art references to arrive at the claimed invention. Further Applicants argue that the cited references nor any combinations thereof teach all limitations of pending claims 1-5 teach "subjecting the extracted nucleic acids to PCR using SEQ ID NO: 1 and SEQ ID NO:2".

Applicants also argue that the present application describes Applicants' discovery that a PCR based assay using the primers of SEQ ID NO: 1 and SEQ ID NO:2 results in a sensitive and reliable method for detecting Map in an animal subject and that the instant application demonstrates that a PCR assay that includes primers having the sequences of SEQ ID NO: 1 and 2 is more sensitive than a PCR assay using only primers P90 and P91. Applicants argue that the IS900 region is 1.45kb in length and thus a very large number of possible primer sequences exist for amplifying this region and none of the cited references nor combinations thereof provide any suggestion or motivation to one of skill in the art to use the particular primers SEQ ID NO:1 and SEQID NO:2.

Applicants' arguments have been carefully considered but are not found persuasive.

The combinations of the references as set forth supra and in the previous office action mailed 10/31/07 render the instantly claimed method obvious. The sequence of the IS900 region is known (Green et al, cited last action) and the art teaches that a variety

of primers are designed to this region to detect Map infection (Vary et al, Corti et al, Herrewegh et al Erume et al and Englund et al, cited in previous action). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because the art teaches PCR amplification of the IS900 region of Map is used to detect MAP infection and the art teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani et al (cited in previous action) teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Also, Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design highly specific primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success. *KSR* forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board Decision *Ex parte Smith*, --USPQ2d--,slip op. at 20, (Bd. Pat. App.& Interf. June 25, 2007 (citing *KSR*, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>) and in view of the teachings in the art as combined as set forth supra and as set forth in the office action mailed 10/31/07, the instant primer SEQ ID NO: 1 and SEQ ID NO: 2 (and the claimed

method for detection Map infection) are obvious over the disclosed sequence of the IS900 region.

As to Applicants' discovery that a PCR based assay using the primers of SEQ ID NO: 1 and Seq ID NO: 2 results in a sensitive and reliable method for detecting Map in an animal subject and that the instant application demonstrates that a PCR assay that includes primers having the sequences of SEQ ID NO: 1 and 2 is more sensitive than a PCR assay using only primers P90 and P91, this is not found persuasive. The instant specification does not teach a PCR assay using SEQ ID NO: 1 and SEQ ID NO: 2 alone. The specification teaches a nested PCR using a first set of primers i.e. P90 and P91 and then a second set of primers i.e. SEQ ID NO: 1 and SEQ ID NO: 2. Said nested PCR results in a more sensitive assay. The method of the instant claims does not involve a nested PCR. The claims recite "...subjecting the extracted nucleic acids to PCR using primers SEQ ID NO:1 and SEQ ID NO:2, wherein the *presence of an amplification product specific for Mycobacterium* avium subsp. Paratuberculosis (Map) in the PCR mixture indicates that the animal is infected with MAP". While, the specification teaches results of a PCR assay using 2 sets of primers i.e. a first set (P90 and P91) and followed by a second set (SEQ ID NO: 1 and SEQ ID NO: 2) (See p. 2 lines 9-22, p. 11 table 1 see second set of primers) there is no disclosed PCR assay comparing sensitivity using the primer set SEQ ID NO: 1 and SEQ ID NO: 2 compared to primer set P90/P91. Any improved advantage that the instant primer set of SEQ ID NO: 1 and SEQ ID NO: 2 has over the primers of the art in detecting Map infection must be demonstrated by a head to head comparison. Applicant has the burden of indicating

how the claimed invention relates to the prior art and by submitting examples reasonably commensurate in scope with the claimed subject matter, establishing that the differences are in fact unexpected and unobvious and of statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318 (BPAI 1992). Applicants have not demonstrated any unexpected and obvious differences commensurate in scope with the instant claims that are of statistical and practical significance over the methods of the prior art.

Status of Claims

Claims 1-5 are rejected. No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645